

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement under 35 U.S.C. § 121, the Examiner has required restriction to one of two inventions embodied by the following groups of claims:

- I. Claims 1-13, drawn to screening assays for HIV antibodies, classified in Class 435, subclass 5;
- II. Claims 14 and 16-25, drawn to peptides of HIV, classified in Class 530, subclass 324.

Applicants elect to prosecute Group I, claims 1-13, with traverse, without prejudice to Applicants' right to file a divisional or related application to the claims of the non-elected group. Further, Applicants elect for prosecution on the merits the species of peptide BRU124F1X. Claims 1, 12, 13, and 14 are generic. Applicants note that upon an indication of allowability of a generic claim, a reasonable number of additional species will be considered and can be claimed in the same application as provided by 37 CFR §141.

REMARKS

Claims 1-14 and 16-25 are currently pending. Claim 15 has been previously canceled. Claims 14 and 16-25 are withdrawn as directed to a non-elected group of claims.

The Examiner has noted that pages 24-25 of the specification are missing from the file record. A copy of the postcard receipt confirming receipt of 26 pages of description is enclosed for the Examiner's review. For the Examiner's convenience copies of pages 24 and 25 of the specification are enclosed herewith.

Response to Sequence Requirement

In response to the "Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures" included with the Request for Restriction, enclosed please find a Sequence Listing, pages 1-4, to be made of record in the application. Also enclosed is a computer diskette containing the sequence listing on a computer readable format. Pursuant to 37 CFR §1.821(f) and (g), it is believed that the content of the paper sequence listing and the computer readable sequence

listing are the same. Further, the present submission of the sequence listing and computer diskette are not believed to constitute new matter.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: 11 January 2002

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SE 5010932 v1

TABLE 1C

**COMPARISON OF HIV-1/2 WESTERN BLOT ALL BAND POSITIVE
AND INDETERMINATE SAMPLE REACTIVITIES IN ELISA WITH POL
ONLY COATED PLATES AND FOUR PEPTIDE COATED PLATES**

Sample	4 Peptides*			HIV-1 pol(BRU124F3X) Only			HIV-2 pol (ROD124C5X) Only			HIV-1/2 Viral Lysate***	
	A450/A630	S/CO	Pos/Neg**	A450/A630	S/CO	Pos/Neg**	A450/A630	S/CO	Pos/Neg**	S/CO	Pos/Neg**
PC-1	1.610	4.8	P	1.503	3.0	P	0.441	0.8	N	N.A.	N.A.
PC-2	1.639	4.9	P	1.539	3.1	P	0.451	0.9	N	N.A.	N.A.
	1.259	3.8	P	0.307	0.6	N	0.438	0.8	N	N.A.	N.A.
	1.221	3.7	P	0.301	0.6	N	0.560	1.1	P	N.A.	N.A.
NC	0.093	0.3	N	0.254	0.5	N	0.279	0.5	N	N.A.	N.A.
	0.091	0.3	N	0.265	0.5	N	0.302	0.6	N	N.A.	N.A.
Cut-off	0.332	N.A.		0.500	N.A.		0.531	N.A.		N.A.	N.A.
HIV-1 WB Pos.											
SAL040	2.985	9.0	P	2.956	5.9	P	2.709	5.1	P	>8.0	P
SAL041	3.028	9.1	P	2.876	5.8	P	2.555	4.8	P	>8.0	P
SAL059	2.957	8.9	P	2.796	5.6	P	2.238	4.2	P	>8.0	P
SAL063	3.009	9.1	P	2.790	5.6	P	2.714	5.1	P	>8.0	P
SAL064	2.934	8.8	P	2.893	5.8	P	2.865	5.4	P	>8.0	P
HIV-2 WB Pos.											
52	2.972	9.0	P	2.738	5.5	P	2.669	5.0	P	>8.0	P
GB92000128	2.939	8.9	P	2.698	5.4	P	2.872	5.4	P	>8.0	P
GB92000152	2.904	8.7	P	2.633	5.3	P	2.743	5.2	P	>8.0	P
GB92000154	3.011	9.1	P	2.677	5.4	P	2.857	5.4	P	>8.0	P
GB92000158	3.061	9.2	P	2.723	5.5	P	2.930	5.5	P	>8.0	P

TABLE 1C (continued)

**COMPARISON OF HIV-1/2 WESTERN BLOT ALL BAND POSITIVE
AND INDETERMINATE SAMPLE REACTIVITIES IN ELISA WITH POL
ONLY COATED PLATES AND FOUR PEPTIDE COATED PLATES**

Sample	4 Peptides*				HIV-1 pol (Bru124F3X) Only			HIV-2 pol (ROD124C5X) Only			HIV 1/2	
	A450/A630	S/CO	Pos/Neg**		A450/A630	S/CO	Pos/Neg**	A450/A630	S/CO	Pos/Neg**	S/CO	Viral Lysate*** Pos/Neg**
HIV-1 Indeterminates												
B3113	0.094	0.3	N		0.346	0.7	N	0.253	0.5	N	3.2	FP
B5813	0.063	0.2	N		0.303	0.6	N	0.244	0.5	N	3.0	FP
B5885	0.063	0.2	N		0.152	0.3	N	0.154	0.3	N	3.1	FP
B7045	0.062	0.2	N		0.241	0.5	N	0.208	0.4	N	3.5	FP
C000127	0.050	0.2	N		0.172	0.3	N	0.177	0.3	N	3.1	FP
C000214	0.056	0.2	N		0.157	0.3	N	0.155	0.3	N	5.4	FP
C000455	0.065	0.2	N		0.136	0.3	N	0.179	0.3	N	5.4	FP
HIV-2 Indeterminates												
B3123	0.051	0.2	N		0.142	0.3	N	0.188	0.4	N	3.2	FP
B5805	0.074	0.2	N		0.203	0.4	N	0.276	0.5	N	3.8	FP
B5810	0.053	0.2	N		0.204	0.4	N	0.205	0.4	N	4.3	FP
B5826	0.049	0.1	N		0.145	0.3	N	0.177	0.3	N	3.0	FP
B5832	0.057	0.2	N		0.183	0.4	N	0.195	0.4	N	3.2	FP
B5875	0.056	0.2	N		0.254	0.5	N	0.286	0.5	N	3.8	FP
B6312	0.027	0.1	N		0.150	0.3	N	0.155	0.3	N	2.8	FP

* 4 peptides = MNGC (1.23ug/ml); 41-2-3GC (0.64ug/ml); BRU124F3X (0.25ug/ml); ROD124C5X (0.125ug/ml)

HIV-1 pol (BRU124F3X) Only and HIV-2 pol (124C5X) Only = 1.0ug/ml each

HIV-1 and HIV-2 WB Pos. = All band Western blot Positive samples

HIV-1 and HIV-2 Indeterminates = Western blot Indeterminates

** In Pos./Neg. columns : P = Positive; N = Negative; FP = False Positive

*** Genetic Systems® HIV-1/2 EIA (FDA approved)

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to these regulations, published at 114 O 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other: _____

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Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.



SEQUENCE LISTING

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<110> Coleman, Patrick F.
Chong-Dug Su, Peter
Monji, Nobuo
Cole, Carol-Ann

<120> SYNTHETIC ANTIGEN FOR THE DETECTION OF ANTIBODIES
IMMUNOREACTIVE WITH HIV VIRUS

<130> 2558P-20-1

<140> 09/515,014

<141> 2000-02-29

<150> 08/904,826

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35